K042507

SEP 27 2004

# 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
August 10, 2004

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Yong-gee, Han
ICM Co. Ltd. Medical Business Division
ICM Building, 15F, #809-10 Yeoksam 1-dong, Gangnam-gu,
Seoul 135-931, Republic of Korea

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

| | |
|---|---|
| Trade Name: | UbiPACS™ |
| Common Name: | Picture Archiving Communications System |
| Device Classification: | 892.2050 |
| Name: | System, Image Processing |

Predicate Device: 21 CFR 807. 92(a)(3)

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|---|---|
| Device Classification Name | SYSTEM, IMAGE PROCESSING, RADIOLOGICAL |
| Regulation Number | 892.2050 |
| 510(k) Number | K022710 |
| Device Name | SmartPACS™ |
| Applicant | Taiwan Electronic Data Processing Corporation |
| Product Code | LLZ |
| Decision Date | 10/11/2002 |
| Decision | SUBSTANTIALLY EQUIVALENT (SE) |

Device Description: 21 CFR 807 92(a)(4)

The system is a server-based software application.

UbiPacs™ is a distributed image management system that manages the archival, retrieval, and distribution of medical images within a Picture Archiving and Communication System (PACS) environment. UbiPacs™ provides network access to patients' current and historical radiological images and relevant examination data. The system is designed for facilitating the clinical practice of radiologists and physicians. UbiPacs™ implementation is based on the Digital Imaging and Communication in Medicine (DICOM) standard. The standard allows communications of images and relevant information such as patient demographics and examination data between the system and other DICOM-

compliant imaging devices such as CT scanners, MR imager, CR systems, digital modalities and image viewing workstations.

Indications for Use: 21 CFR 807 92(a)(5)

UbiPACS™ by ICM Co. Ltd. is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.
Typical users of this system are trained professionals, i.e. physicians, radiologists, nurses, medical technicians, and assistants.

Technological Characteristics: 21 CFR 807 92(a)(6)

UbiPacs™ is a software application and does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for UbiPacs™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. UbiPacs™ will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2004

ICM Co., Ltd.
% Mr. N. E. Devine, Jr.
Responsible Third Party
Entela, Inc.
3033 Madison Ave., SE
GRAND RAPIDS MI 49548

Re: K042507
Trade/Device Name: UbiPACS™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 15, 2004
Received: September 15, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K042507

Device Name: UbiPACS™

Indications for Use:

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Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042507